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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/464,528 12/15/99 FALCO

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EXAMINER

HM22/0705

LYNNE M CHRISTENBURY
E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENTS
WILMINGTON DE 19898

COLLINS, C

ART. UNIT

PAPER NUMBER

1638

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/464,528

Applicant(s)

FALCO ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. The Amendment filed April 12, 2001, paper no. 8, has been entered.
2. Claims 1, 2, 3, 7, and 8 have been newly amended.
3. Claim 12 has been cancelled.
4. Claims 1-11 are pending.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The objection to claim 2 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, as stated in the last office action, is withdrawn in view of Applicants' amendment of claim 2.
7. The objection to claim 7 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, as stated in the last office action, is withdrawn in view of Applicants' amendment of claim 7.
8. The rejections of claim 12 under 35 U.S.C. 112, first paragraph, as stated in the last office action, are withdrawn in view of Applicants' cancellation of claim 12.
9. The rejections of claims 1 and 8, and dependent claims 2-7 and 9-11, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated in the last office action, are withdrawn in view of Applicants' amendments of claims 1 and 8.

Claim Rejections - 35 USC § 112

10. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. The claims are drawn to an isolated nucleic acid fragment comprising a promoter having at least 80% identity with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16, or a promoter which hybridizes with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16. The claims are also drawn to a chimeric gene, a plant and seed comprising said isolated nucleic acid fragment.

12. However, the specification does not set forth what structural or physical features are required in an isolated nucleic acid fragment comprising a promoter having at least 80% identity with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16, or a promoter which hybridizes with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16. The specification only discloses an isolated nucleic acid fragment (SEQ ID NO:6) that has promoter function in transgenic plant cells of *Arabidopsis* and corn (Examples 4-7 pages 19-24). The identities of the claimed isolated nucleic acid fragments and transgenic plants and seeds are uncertain. The structural or physical features of the claimed isolated nucleic acid fragments and transgenic plants and seeds cannot be ascertained in the absence of information about the functional activity of the nucleic acids they comprise. The specification does not disclose whether any DNA fragments other than SEQ ID NO:6 will function as a promoter in a transgenic cell or plant.

13. That another isolated nucleic acid having homology to SEQ ID NO:6 will function as a promoter cannot be assumed merely on the basis of sequence homology (Kim et al. and Benfey et al., as discussed in the previous Office Action).

14. Because the ability of a particular nucleic acid sequence to function as a promoter can vary depending on the mutation of even a single nucleotide in that nucleic acid sequence, the location of

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that nucleic acid sequence relative to other nucleic acid sequences, and the species of plant into which that nucleic acid sequence is introduced, and because the specific structural elements that are critical for promoter function of the claimed isolated nucleic acid fragments are not disclosed in the specification and were not known in the art at the time the invention was made, the claimed isolated nucleic acid fragments and transgenic plants and seeds are not adequately described.

15. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed isolated nucleic acid fragments and transgenic plants and seeds, and given the high level of unpredictability in this art of defining DNA fragments that would function as promoters, one skilled in the art would not have been in possession of the claimed isolated nucleic acid fragments and transgenic plants and seeds at the time this application was filed.

16. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid fragment comprising a promoter that is SEQ ID NO: 6, does not reasonably provide enablement for an isolated nucleic acid fragment comprising a promoter having at least 80% identity with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16, or a promoter which hybridizes with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

17. The claims are drawn to an isolated nucleic acid fragment comprising a promoter having at least 80% identity with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16, or a promoter which hybridizes with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16. The claims are also drawn to a chimeric gene, a plant and seed comprising said

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isolated nucleic acid fragment. In addition, the claims are drawn to a method of expressing at least one heterologous nucleic acid fragment in a plant cell by transforming a plant cell with a chimeric gene comprising said isolated nucleic acid fragment.

18. The specification only discloses that the isolated nucleic acid fragment of SEQ ID NO:6 has promoter function in transgenic plant cells of *Arabidopsis* and corn (Examples 4-7 pages 19-24).

The specification does not teach whether any other isolated nucleic acid fragment has promoter function. Furthermore, the specification does not set forth any specific structural characteristics that are critical for the function of the claimed promoters, such as the identification of specific nucleotides in a claimed isolated nucleic acid fragment whose alteration affects promoter activity.

19. Guidance for making and using the claimed invention is necessary for enablement because the ability of a particular nucleic acid sequence to function as a promoter is highly unpredictable on the basis of nucleotide sequence information alone, and because the ability of a particular nucleic acid sequence to function as a promoter in different transgenic plants is also highly unpredictable (Kim et al. and Benfey et al., as discussed in the previous Office Action). Because the ability of the claimed isolated nucleic acid fragments to function as promoters is not described by analogy or by example, the claimed invention is not enabled by the specification in the absence of further guidance or example.

20. Given the unpredictability of a particular isolated nucleic acid fragment functioning as a promoter, the absence of guidance in the specification for making and using the claimed promoters, the lack of working examples, and given the breadth of the claims which encompass promoters having at least 80% identity with any of the nucleotide sequences set forth in SEQ ID NOS: 6, 14, 15, or 16, and promoters which hybridize with any of the nucleotide sequences set forth in SEQ ID

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NOS: 6, 14, 15, or 16, as well as plants and seeds comprising said promoters, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 101

21. Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

22. Claim 7 is drawn to seed, but is not limited to seed that comprises the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that plant. In addition, given that there is no indication that there would be any other distinguishable characteristics of the claimed seed, it is unclear whether the claimed seed would be distinguishable from seed that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the seed comprises in their genome the construct that was introduced into the parent plant would overcome the rejection.

Remarks

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

June 29, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

